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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,144

10/17/2006

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EXAMINER

LEE, JAE W

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,144	<b>Applicant(s)</b> SHIMOMURA ET AL.	
	<b>Examiner</b> JAE W. LEE	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02/19/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31,32 and 52-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-15,18-28,33-38,41,42 and 45-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31,32 and 52-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application status***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/19/2009 has been entered.

In response to the previous Office action, a final rejection (mailed on 08/05/2008), Applicants filed a response and amendment received on 02/19/2009. Said amendment canceled Claims 16, 17, 29, 30, 39, 40, 43 and 44, amended Claim 31, and added Claims 55-56. Thus, Claims 31, 32 and 52-56 are at issue and present for examination.

Applicants' arguments filed on 02/19/2009, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

It is noted by the Examiner that Claims 1-15, 18-28, 33-38, 41, 42 and 45-51 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn

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to a non-elected invention in the previous Office actions, a non-Final rejection (mailed on 09/19/2007).

### ***Specification***

The specification is objected to because the title, "Novel Protein", is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. 606.01).

### ***Claim Objections***

The previous objection of Claim 31 for reciting the phrase, "disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality," is withdrawn by virtue of Applicants' amendment.

Appropriate correction is required.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of Claims 31, 32 and 52-54 for reciting the phrase, "80% or more to the amino acid sequence starting at amino acid No. 1 in the amino acid sequence shown by SEQ ID NO: 2 or 4," is withdrawn because Applicants have deleted the noted phrase.

The previous rejection of Claims 31, 32 and 52-54 for reciting the phrase, "SEQ ID NO: 2 or 4, or a salt thereof, into contact," is withdrawn by virtue of Applicants' amendment.

Claims 31, 32 and 52-56 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 32 and 52-56 recite the phrase "comprising an amino acid sequence having an identity of the amino acid sequence starting at amino acid No. 1 in the amino acid sequence shown by SEQ ID NO: 2 or 4" is unclear and indefinite. It is unclear what degree of identity, i.e., 0-100%, "an amino acid sequence" has. Since it appears that Applicants intention was to limit the scope of the protein "to the exact sequences of SEQ ID NO: 2 or 4" according to page 13, last paragraph of the Applicants' remarks, filed on 02/19/2009, and in the interest of advancing prosecution, the Examiner has interpreted the noted phrase as "comprising the amino acid sequence of SEQ ID NO: 2 or 4". It is noted that failure to address this issue will result in rejections under 112 1st paragraph.

Claims 52 and 53 are unclear because the scope of claims 52 and 53 is either broader or does not further limit the scope of 31 which they depend from. Since the scope of "the protein" of claim 31 is interpreted as "comprising the amino acid sequence of SEQ ID NO: 2 or 4" as noted above, the scope of claim 52, i.e., "having an identity of 90%...", is actually broader, and the scope of claim 53 does not further limit the scope

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of claim 31. It is suggested that Applicants cancel these claims or clarify the scope of these claims so that it properly further limits claim 31. In the interest of advancing prosecution, claims 52 and 53 are not given any patentable weight.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of Claims 31, 32, 52 and 54 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn based on the Examiner's interpretation of claims 31, 32 and 52-56 (see above 112 2<sup>nd</sup> paragraph rejections).

### ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 32 and 52-54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lanctot et al. (US Patent Application Publication, US 2003/0125258, published Jul. 3, 2003).

The instant claims are drawn to a screening method for a prophylactic/therapeutic substance for a disease associated with abnormal differentiation of skeletal muscle cell and/or metabolic abnormality, which comprises bringing a protein, or a salt thereof, comprising the amino acid sequence of SEQ ID NO: 2 or 4 into contact with its receptor in the presence or absence of a test substance, and selecting the test substance that changes the ability of said protein or salt thereof to bind to said receptor as a candidate for a prophylactic/therapeutic substance for a disease associated with abnormal differentiation of skeletal muscle cell and/or metabolic abnormality.

The rejection was stated in the previous office action as it applied to previous claims 31, 32 and 52-54. In response to this rejection, Applicants have amended claim 31, and added claims 55-56, and traverse the rejection as it applies to the newly amended claims.

The instant rejection of record is reiterated, with minor changes to reflect the new amendment to claims, for Applicants' convenience below.

The reference of Lanctot et al. specifically teaches a screening method comprising contacting BP-1 proteins, with a receptor in the presence of a molecule that may modulate binding of BP-1 proteins to a receptor (see paragraph [0144] under "x) Screening Methods Using BP-1 Products") for a disease associated with bone disorder

or osteoporosis. Further, as previously noted, the secreted human BP-1 protein taught by Lanctot et al. is identical to Applicants' SEQ ID NO: 2 or 4 (See SCORE, 20070817\_151735\_us-10-561-144-2.rag and 20070817\_151735\_us-10-561-144-4.rag).

Applicants argue that Lanctot et al. do not anticipate Claim 31 because it specifically refers to the limitation of "a disease associated with abnormal differentiation of skeletal muscle cell and/or metabolic abnormality" which is not taught by Lanctot et al.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. In the instant case, *the active steps of the methods taught by Lanctot et al. are no different* from those of Applicants' claimed methods (emphasis added). Further, while the limitation regarding "prophylactic/therapeutic substance" is in reference to the compound that modifies the binding activity of the protein to the receptor, the claim does not recite any active step wherein one selects a compound having the specific functional limitations, i.e., suppression of sugar uptake or glycogen synthesis under insulin stimulation in skeletal muscle cells, among other substances that modulate the binding activity of the protein to the receptor. In fact, the claim 31 recites that any compound that changes the binding activity of the protein to the receptor for *any disease associated with any metabolic abnormality* is a candidate for a "prophylactic/therapeutic substance." As such, the methods taught by Lanctot et al. meet the limitations of the claims 31, 32 and 52-54 because the test compound of Lanctot et al. is a candidate for a prophylactic/therapeutic substance for any disease associated with any metabolic



abnormality. Therefore, Lanctot et al. anticipate the claims 31, 32 and 52-54 for the reasons provided herein and in the previous office actions.

### ***Conclusion***

Claims 31, 32 and 52-56 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

This office action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/

Examiner, Art Unit 1656

/Rebecca E. Prouty/  
Primary Examiner,  
Art Unit 1652